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# Design and Methods in a Multi-Center Case-Control Interview Study

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**Abstract:** We conducted a case-control study in ten areas of the United States in which a total of 2,982 bladder cancer patients and 5,782 population controls were interviewed. We employed a variety of existing and new techniques to reduce bias and to monitor the quality of data collected. We review here many of the design elements and field methods that can be generally applied in epidemiologic studies, particularly multi-center interview studies, and explain the reasons for our selection of the methods, instruments, and procedures used. (*Am J Public Health* 1984; 74:52–56.)

*Introduction*

This report describes the design and methods used in a recent case-control interview study, the National Bladder Cancer Study. Researchers at ten cancer registries in the United States and the National Cancer Institute conducted the study to clarify the role of artificial sweeteners and other exposures in human bladder cancer.[1–14] The 18-month study was conducted in 10 widely dispersed centers and employed 130 interviewers and 40 coders. In view of the increasing use and high cost of multi-center interview studies, we think it is useful to comment on the various methods employed.

*Materials and Methods*

We chose a population-based design in which all incident cases occurring in ten geographic areas were identified by tumor registries, and controls were drawn at random from the same populations. We chose this design rather than a clinic- or hospital-based design because dietary habits, including saccharin consumption, might be atypical among ill people.* We did not choose a death-certificate based design for the same reason and because of the difficulty of obtaining dietary information from surrogate respondents. The population-based design also permitted direct estimation of the proportion of all cases attributable to a given exposure.

The population-based design was feasible only because a population sample of controls could be economically selected and because population-based cancer registries capable of rapid ascertainment of all bladder cancer cases covered substantial parts of the US.**

**Cases**

Tumor registry staff identified all residents aged 21–84 who were first diagnosed with histologically confirmed bladder cancers (or bladder papillomas not specified as benign) during a one-year period, using one or more of the following resources: searches of pathology logs; searches of hospital tumor registry files; searches of hospital diagnostic lists such as those of the Professional Activities Study, PAS; and periodic polling of local urologists. Pathology logs provided the best primary mechanism for complete and rapid ascertainment. Hospital tumor registry files were not reliably complete or timely. Diagnostic lists were complete (except for cases diagnosed at autopsy) but not timely, while reports from urologists were often timely but not complete.

We sought to identify cases as soon as possible after they were diagnosed in order to minimize the number of subjects who died or became too ill before we could interview them.*** To measure how quickly and how completely we were identifying cases, we computed an expected cumulative distribution of cases by month of diagnosis, based on previous years' incidence data from that area, and compared it each month to the observed cumulative distribution. The cumulative monthly distributions permitted us to estimate whether the then-unidentified cases had occurred recently. A similar hospital-specific analysis helped to trace losses or lags to particular hospitals.

Altogether, 6.9 per cent of the cases died before interview (range = 5.2–10.3 per cent) and 7.0 per cent became too disabled to be interviewed (range = 2.0–9.6 per cent). On the average, 111 days elapsed between diagnosis and interview (range = 53–145). The ranking of areas by the fraction of cases who died before interview was positively correlated with the ranking by elapsed days. Several registries in large rural areas had long lags between diagnosis and identification, but not necessarily between identification and interview. The registries that used pathology logs as the primary mode of case-finding had shorter lags between diagnosis and identification.

**Population Controls**

Within each geographic area, we drew a random sample of residents, stratifying the sample on age (in five-year intervals) and sex. We selected approximately twice as many controls as cases in order to gain statistical power in the examination of high-risk subgroups of the total study group. In New Jersey, we reduced the ratio to 3:2 because of the large number of cases; in Detroit we reduced it to 1:1 because of the inclusion of a separate hospital-based control group.

The most difficult aspect of control selection was procedural, namely selecting a sampling frame that would yield a true probability sample and not be prohibitively expensive. We considered five alternative sampling frames: 1) area-survey lists of dwellings; 2) telephone-survey lists of house-

*In one area, we interviewed a hospital-based control group and found this to be so.[15]

**Nine of the participating registries were part of the Surveillance Epidemiology and End Results (SEER) network and covered the populations of four states (Connecticut, Iowa, New Mexico, Utah) and five metropolitan areas (Atlanta, Detroit, New Orleans, San Francisco, Seattle). The tenth covered the state of New Jersey with a rapid reporting system for bladder cancer mandated by state law.

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***The observed median time of survival is about four years for White patients and one year for Black patients.[16]

holds; 3) voter registration lists; 4) motor vehicle registration lists; 5) the Health Care Financing Administration (HCFA) roster of older Americans. Options 1 and 2 lead first to households and then to individuals (multi-stage sampling schemes). Options 3, 4, and 5 lead directly to individuals (single-stage schemes).

Area-survey lists of dwellings already existed in only one of the study areas. They are very expensive to create and expensive to use to draw a sample of older people.

Telephone surveys are subject to non-response and do not include households without phones.[17] In most of the areas, more than 90 per cent of the population aged 25–64 lived in households with telephones.[18] In most states, telephone coverage of the Black population was 5 to 10 percentage points lower than coverage of the White population. We estimated that the costs would be much lower than for area-surveys.

For both of the multi-stage sampling schemes, the cost of identifying a control depends upon the number of households that must be contacted to locate the control. The restrictiveness of the sampling selection criteria and the demographic profile of the population determine the difficulty and therefore the cost of identifying controls. For example, older men are more expensive to locate than other people because there are fewer of them per household. Since the incidence of bladder cancer is highest in older men, we needed to select many of these expensive controls.

Voter registration lists typically exclude about one-third of the adult population,[19] do not list age, often list old addresses, usually are not computerized, and are not routinely revised to remove people who have moved or died.

Motor vehicle registry lists typically exclude 10–15 per cent of the population (depending upon age) and have addresses that are about two years old, on average, but they are often computerized.[20]

The HCFA estimated that its 1978 roster covered 98 per cent of the US population older than 64. The roster had not been used for epidemiologic research before this study, so we were uncertain how current it would be and how feasible to use. The file was computerized and included age and sex, which made stratified sampling feasible. It was also clearly the most economical resource. For controls aged 21–64, the best available sampling frame was the telephone-based sample of households.

#### Selecting Controls by Random Digit Dialing

In New Mexico, a computerized list of all telephone numbers (listed and unlisted) was available. In Utah, a sample of telephone numbers was generated by randomly selecting from the telephone books and permuting the last two digits. Telephone-surveying for the other eight areas was conducted from Bethesda, Maryland, using the variant of random-digit-dialing developed by Waksberg.[21] For all ten areas, we drew the sample of controls aged 21–64 in three stages: 1) we sampled residential telephone numbers at random; 2) an interviewer called each telephone number and asked the name, sex, and age of every household member aged 21–64 and the address of the household ("screening"); 3) we drew a random sample, weighted by the expected age and sex distribution of the cases, of the individuals enumerated on the pooled household censuses.‡

We did not wish to select husband-wife pairs into the control group because of the probable correlation between the personal habits (e.g., saccharin consumption) of husbands and wives[22] and because of their potential unwillingness to participate. In the first 1,300 households that we called in which there was at least one person aged 21–64, there were 397 men and women who would have been eligible controls. Of the women so drawn, 42 per cent were wives of men also drawn into the sample. This pattern appeared because of the relatively large numbers of older men and older women we needed, people who tend to be found in the same households. Therefore, before sampling individuals (stage 3), we randomly separated households into two pools. From one pool, we drew only male controls; from the other, only female.‡‡

#### Data Collection

Apart from the general problems of interview methods and questionnaire design,[23-25] specal problems arise in case-control studies of cancer, such as whether to make the interviewers unaware of which respondents are cases, how to describe the study, and where to conduct the interviews. We contacted physicians before contacting cases and introduced the study to subjects in highly general terms while avoiding mention of cancer or specific exposures. Interviewers were told that cases were ill, but we did not identify their disease as bladder cancer. We did not make the interviewers "blind" to whether a subject was a case or a control because our previous studies with cancer patients and healthy controls showed that interviewers rarely remained unaware of the subject's status. We chose in-person interviews rather than telephone or mailed questionnaires because of the length and complexity of the questionnaire. We interviewed both cases and controls in their homes to assure comparability of setting.

#### Response Rates: Random Digit Dialing

To select controls younger than age 65 from household censuses obtained from telephone screening, we called 25,826 working, non-business telephone numbers. At 88 per cent of these telephone numbers, a person answered who was willing to give the names and ages of household members aged 21–64 and, if someone in the household was selected as a control, the household address (Table 1). If a person refused, the telephone interviewer recorded whether the refusal was mild, firm, or hostile. The response rates to telephone screening were initially 75–80 per cent, but active efforts to persuade initial refusers to participate raised the final response rate to 88 per cent. Seventy per cent of the non-responses were refusals; the remainder were because of no answer, foreign language, deafness, illness, and other reasons.

One disadvantage of selecting controls by telephone and then attempting personal interviews is that controls have, in effect, two chances to refuse (or for someone in their household to refuse for them). Our estimate of the true overall response rate among controls aged 21–64 was 75 per cent (the product of the screening response rate and the personal interviewing response rate—88 per cent × 85 per cent).

‡If the person answering the phone gave the sexes and ages but not the address, the household members were eligible to be drawn as controls. If such a person was drawn, an interviewer tried again to determine the address.

‡‡To draw males and females from the same pool of households and then exclude one spouse when a spouse-pair was drawn would have linked a person's probability of selection to his age and the structure of his household.

**TABLE 1—Geographic Variation in Response Rates, for Telephone Screening of Households and for Home Interviews**

| Geographic Areas | Telephone Screening | | Home Interviews: Cases | | Home Interviews: Controls | |
|---|---|---|---|---|---|---|
| | % | No. | % | No. | % | No. |
| Atlanta | 87 | 1770 | 70 | 152 | 80 | 335 |
| Connecticut | 87 | 3130 | 69 | 562 | 84 | 1044 |
| Detroit | 89 | 2368 | 70 | 540 | 85 | 610 |
| Iowa | 93 | 2778 | 82 | 430 | 89 | 846 |
| New Jersey | 86 | 7010 | 75 | 1258 | 83 | 2015 |
| New Mexico | 86 | 603 | 78 | 87 | 86 | 201 |
| New Orleans | 85 | 957 | 83 | 99 | 75 | 223 |
| San Francisco | 86 | 4865 | 64 | 561 | 79 | 927 |
| Seattle | 92 | 1627 | 72 | 248 | 74 | 451 |
| Utah | 93 | 718 | 79 | 149 | 86 | 333 |
| TOTAL | 88 | 25826 | 73 | 4086 | 83 | 6985 |

### Response Rates—Interviewing

Tables 1 and 2 show personal interviewing response rates for cases and controls.‡‡‡ The rates varied among the study centers and between cases and controls, ranging from 64 per cent to 86 per cent. They also varied with season (falling in August and December) and with current events (falling markedly in San Francisco after the Jonestown tragedy). Among cases, interviewing response rates were higher for men than for women and for people aged 35–64 than for older or younger people. Among controls, interviewing response rates were similar for men and women and lower for subjects aged 75–84 than for younger subjects. As Table 3 shows, the major sources of non-response were subject refusal, disability, and death. Only 3 per cent of the cases were not interviewed because we did not get clearance from physicians.

In Detroit, separate proxy interviews were sought for subjects who had died or become too disabled for an interview (not included in the analysis). Inclusion of proxy interviews increased the Detroit response rate from 73 per cent to 80 per cent. Response rates for proxies were lower than those observed for original subjects (cases: 67 per cent versus 70 per cent, respectively; population controls aged 65–84; 76 per cent versus 85 per cent, respectively).

For 84 respondents who spoke no English, we were able to obtain an interview by using a translator. In New Mexico, we also used a Spanish questionnaire. Many older subjects who initially declined to be interviewed because they were ill agreed to be interviewed when we recontacted them several weeks or months after the first contact. For 345 respondents, we obtained an interview only after four or more trips to the study subject's home.

### Interviewing

Within each center, the interviewer supervisor identified new cases, contacted physicians, mailed letters to subjects, assigned work to interviewers, monitored interviewers' response rates and productivity, edited questionnaires, and reviewed all refusals. If an interviewer's response rate was low, additional training was begun.

The quality of completed interviews was monitored by editing all of the questionnaires for legibility, completeness, time, and marks indicating that necessary probing was done, by checking each questionnaire for 19 critical items. (If any were missing, the supervisor telephoned the subject to collect the missing data.) In addition, 15 per cent of all questionnaires were chosen at random for validation through a brief telephone interview that included a few key questions from the questionnaire.

Weekly activity reports from the area offices to the central office, which noted any change in each subject's status from the previous week, were used to maintain a computerized database from which we computed the proportions of non-response according to reason in each area.

‡‡‡These rates are based only on identified subjects; refusals of households during telephone screening are not reflected in the interviewing response rates for controls aged 21–64.

**TABLE 2—Per Cent of Bladder Cancer Cases and Population Controls Interviewed by Sex, and Age**

| Variables | Cases Interviewed | | Controls Interviewed | |
|---|---|---|---|---|
| | % | Number | % | Number |
| Sex | | | | |
| Male | 75 | 3016 | 83 | 5133 |
| Female | 69 | 1070 | 81 | 1852 |
| Age (years) | | | | |
| 21–34 | 68 | 57 | 84 | 128 |
| 35–44 | 82 | 111 | 80 | 237 |
| 45–54 | 85 | 396 | 85 | 843 |
| 55–64 | 79 | 997 | 84 | 1721 |
| 65–74 | 75 | 1375 | 85 | 2237 |
| 75–84 | 61 | 1150 | 77 | 1819 |
| TOTAL | 73 | 4086 | 83 | 6985 |

### Data Preparation

We prepared a coding manual that included general instruction in coding procedures, specific instructions for this study (editing, critical items to check, decision logs, document control), and the codes for each questionnaire item. For the residential history, there were several possible coding systems available. We chose the General Services Administration (GSA) Locations and Place Names[26] because it could be linked to data on water quality.

We considered two schemes for coding occupation: the 1970 US Census Index[27] and the US Department of Labor's Dictionary of Occupational Titles (DOT).[28] The latter is more detailed and has been linked to a list of chemical and other work exposures.[29] We found that the answers given by respondents in our study rarely gave detail beyond that captured by the Census Index and that the DOT was cumbersome to use. We conducted a test on 968 jobs, coding 370 with the Census Index and 598 with the DOT. Two coders did all of the coding for the test and each used both schemes. The error rates were 6 per cent with Census and 5 per cent with DOT. The Census Index took about five minutes per job, and the DOT took about 10 minutes per job. We therefore decided to use the Census Index. We have subsequently evaluated the Standard Occupational Classification (SOC), a companion to the Standard Industrial Classification (SIC)[30] and found it takes about as long to code one job with the SOC as with the Census Index.

For the industry codes, we considered two schemes—the SIC, and the 1970 Census Index.[28] In a test on 968 questionnaires, the error rates on industries were 2 per cent for SIC and 1 per cent for Census and took about the same time. We chose the Census Index for coding industries primarily because of its ease of use in combination with Census Index for coding occupations.

**TABLE 3—Per Cent Non-Response, According to Reason for Non-Response, by Sex, Age, and Subject Type**

| | Reason for Non-Response | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Variables | Dead | Disabled | Subject Refused | Not Located | Physician Refused | Language Problem | Other Reason | No. |
| Sex | | | | | | | | |
| Male | 3.6 | 3.9 | 7.8 | 2.5 | 1.1 | 0.3 | 0.7 | 8149 |
| Female | 3.1 | 5.7 | 10.2 | 2.3 | 1.4 | 0.1 | 0.8 | 2922 |
| Age (years) | | | | | | | | |
| 21–44 | 0.6 | 1.5 | 10.9 | 4.3 | 1.1 | 0.6 | 0.7 | 533 |
| 45–64 | 1.6 | 1.7 | 9.2 | 2.3 | 1.0 | 0.1 | 0.6 | 3957 |
| 65–84 | 4.8 | 6.2 | 7.8 | 2.4 | 1.3 | 0.2 | 0.8 | 6581 |
| Type | | | | | | | | |
| Case | 6.9 | 7.0 | 6.2 | 2.0 | 3.1 | 0.1 | 1.6 | 4086 |
| Control | 1.4 | 2.8 | 9.8 | 2.7 | — | 0.3 | 0.2 | 6985 |
| TOTAL | 3.5 | 4.4 | 8.4 | 2.5 | 1.2 | 0.2 | 0.7 | 11071 |

Coding was done by 40 coders who were supervised by one supervisor and one assistant. We used separate verification procedures for the occupational coding and the rest of the questionnaire. For the latter, we followed the Bureau of the Census practice[31]—two in ten questionnaires were randomly selected for checking. If more than 6 per cent of the non-occupational items had an error, the other eight questionnaires coded by the same coder during the same period of time were also checked. From each subject's occupational history, one job was coded again, without knowledge of the first coder's decision. If the two coders did not agree, an arbitrator assigned a code. Eight per cent of occupational items had some error corrected. This error rate was the same for cases and controls. Fewer than 1 per cent of the non-occupational items had an error detected.

### *Discussion*

The goals of case-control studies in general[32] and in cancer research in particular[33] have been well described. Threats to validity from non-comparability of cases and controls,[32] from misclassification,[34] and from non-response[35] have also been elucidated. The need to assure comparability[32] and to minimize misclassification,[35] non-response,[35] and observation bias is clear, but the techniques for doing so are less clear. We attempted to apply general principles of quality assessment and assurance to the specific problems of large multi-center case-control studies.

When alternative schemes were available, e.g., in sampling and coding, we conducted small tests to choose the best alternative. We repeated or double-checked a fixed fraction (often 10 per cent) of the work at as many stages of the study as possible, to yield objective measurements of the quality of the work. We made these measurements frequently and while the work was still in progress in order to improve the quality of the study through feedback, retraining, and modification of procedures. We found that the effectiveness and productivity of telephone interviewers, field interviewers, and coders were strongly influenced by continued reinforcement of training. We think the same principles apply in smaller studies, although they may be implemented differently, for example, with manual rather than computerized record-keeping.

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